

NOV 16 2005

**SECTION B: 510(k) SUMMARY**

**Submitter:** Alliance Medical Corporation  
10232 South 51<sup>st</sup> Street  
Phoenix, Arizona 85044

**Contact:** Elizabeth Renken  
Regulatory Affairs Specialist  
(480) 763-5300 (o)  
(480) 763-5310 (f)  
[erenken@alliance-medical.com](mailto:erenken@alliance-medical.com)

**Date of preparation:** September 9, 2005

**Name of device:** *Trade/Proprietary Name: Reprocessed Electrophysiology Catheters*  
*Common or Usual Name: Electrophysiology Catheter or Electrode Recording Catheter*  
*Classification Name: Electrode Recording Catheter*

**Predicate device:**

K Number	Device Description
K894500	Daig Electrophysiology Catheter
K942379	Daig Diagnostic Electrophysiology Catheter
K012708	Reprocessed Electrophysiology Catheters

**Device description:** Diagnostic electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a handpiece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tips of deflectable catheters can be deflected into a curve by manipulating the handpiece; fixed curve catheters have an established distal tip shape.

**Intended use:** Reprocessed Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation, and electrophysiological mapping of cardiac structures.

**Indications statement:** Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures.

**Technological characteristics:**

The design, materials, and intended use of Reprocessed Electrophysiology (EP) Catheters are identical to the predicate devices. The mechanism of action of Reprocessed Electrophysiology (EP) Catheters is identical to the predicate devices in that the same standard mechanical design, materials and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Alliance Medical Corporation's reprocessing of electrophysiology catheters includes removal of adherent visible soil and decontamination. Each individual electrophysiology catheter is tested for appropriate function of its components prior to packaging and labeling operations.

Alliance Medical Corporation's reprocessing of EP Catheters includes removal of adherent visible soil and decontamination. Each individual EP Catheter is tested for appropriate function of its components prior to packaging and labeling operations.

**Performance data:**

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed EP Catheter.

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed EP Catheters perform as originally intended.

**Conclusion:**

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (the Reprocessed Electrophysiology (EP) Catheter) is safe, effective and substantially equivalent to the predicate devices as described herein.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 16 2005

Alliance Medical Corporation  
c/o Ms. Elizabeth Renken  
Regulatory Affairs Specialist  
10232 South 51<sup>st</sup> Street  
Phoenix, AZ 85044

Re: K052603

Trade Name: Reprocessed Electrophysiology Catheters (See Enclosed List)  
Regulation Number: 21 CFR 870.1220  
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe  
Regulatory Class: Class II  
Product Code: NLH  
Dated: September 13, 2005  
Received: September 21, 2005

Dear Ms. Renken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

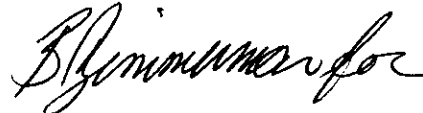
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

List of Models:

<b>St. Jude LiveWire™ Steerable Diagnostic Catheters</b>
401575
401576
401577
401578
401579
401580
401581
401582
401586
401587
401588
401600
401603
401606
401652
401653
401654
401904
401905
401914
401915
401918
401923
401926
401932
401933
401934
401572
401908
401917
401938
401939
401940
401941
401949
401990
401991

## Indications for Use

**510(k) Number** (if known): K052603

**Device Name:** Reprocessed Electrophysiology Catheters

**Indications For Use:** Reprocessed Electrophysiology (EP) Catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Sign-Off)

Division of Cardiovascular Devices

510(k) Number K052603

Alliance Medical Corporation  
Reprocessed EP Catheters  
Traditional 510(k)